



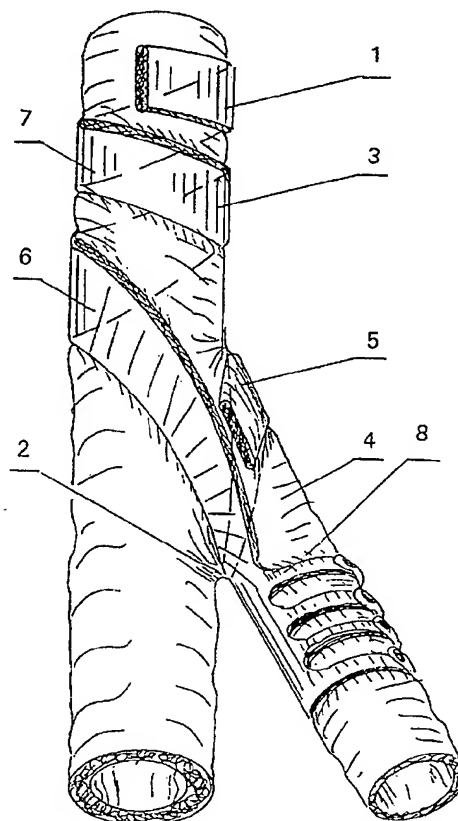
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/EP94/02750 (22) International Filing Date: 18 August 1994 (18.08.94) (30) Priority Data: 106738 19 August 1993 (19.08.93) IL (71) Applicants (for all designated States except US): MIND- E.M.S.G. LTD. [IL/IL]; 64 Hashahar Street, Raanana (IL). BENEDUM, Ulrich, M. [DE/DE]; Ina-Seidel-Bogen 42, D- 81929 Munich (DE). (72) Inventors; and (75) Inventors/Applicants (for US only): SHIFRIN, Edward, G. [IL/IL]; 64 Hashahar Street, Raanana (IL). PORTNOY, Isaak [IL/IL]; Apartment #7, Anne Frank Street, Kfar Sava (IL). ZELMANOV, Salomon [IL/IL]; Apartment #6, 24 Sharl Lutz Street, Haifa (IL). NICKELSHPUR, Gennady [IL/IL]; Apartment #49, 5 Marotem Street, Haifa (IL). MORAG, Baruch [IL/IL]; 7 Eliahu Street, Ramat Gan. (IL). (74) Agent: HASELTINE LAKE PARTNERS; Rosenheimer Strasse 30, D-81969 München (DE).		(81) Designated States: AT, AT (Utility model), AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DE (Utility model), DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>	

(54) Title: DEVICE AND METHOD FOR EXTERNAL CORRECTION OF INSUFFICIENT VALVES IN VENOUS JUNCTIONS

(57) Abstract

Device (1) for external correction of insufficient valves in venous junctions (2), comprising substantially a length of material shaped as a band (3), with a variable rigidity and vein compressing rate (4), said band having at least one main compressing portion (5), an intermediate portion (6) and a fastening portion (7), said main compressing portion (5) being disposable into the vein surface around the insufficient valve.



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DEVICE AND METHOD FOR EXTERNAL CORRECTION OF INSUFFICIENT
VALVES IN VENOUS JUNCTIONS

Background of the Invention

5

1. Field of Invention

The present invention relates to a medical technique and in particular to vein valves correction, applied in treatment of cardiovascular diseases.

10

2. Background of the Invention

Lower limbs varicosity is one of the most common vascular diseases.

In most cases it occurs due to insufficiency of the Sapheno-Femoral Junction (SFJ).

15

In different countries of the world, on the average, from 40% to 60% of women population are affected by lower limbs varicosity.

It is also very important to save these veins for potential application thereof in aorto-coronary bypass or peripheral arterial reconstructions.

20

So far no efficient methods have been developed for the elimination of valves insufficiency and saving the superficial and deep veins, especially in SFJ area.

The simplest and most effective solution of the problem is external compression of the vein around the insufficient valve to reduce the central opening lumen and restore valve function thereof.

25

There are many engineering solution applied in medicine for correcting defects in blood vessels and human hollow organs.

30

Devices and methods are known for reconstruction of affected blood vessels (U.S. Pat. # 5,100,422; U.S. Cl. 606-151, 3/1992, or "VENOUS DISORDERS" by John B. BERGAN and James S. T. YAO, W.B. SAUNDERS COMPANY, Philadelphia, 1991, p. 303-311).

35

Devices are also known for compression of vessels or hollow organs or securing portable medical instruments thereon (U.S. Pat. # 5,160,338; U.S. Cl. 606-157, 11/1992; U.S. Pat. # 5,080,095; U.S. Cl. 128-402, 1/1992; U.S. Pat. # 5,171,252; U.S. Cl. 606-151, 12/1992 or U.S. Pat. # 4,938,765; U.S. Cl. 606-158, 7/1990).

Said devices can compress the vein around the insufficient valve and control, within certain limits, the compression force.

However, said devices cannot be disposed directly on a venous junction, and they do not provide the desired accuracy of compression rate control.

Special devices are further known for occluding the vein (U.S. Pat. # 4,586,501; U.S. Cl. 128-325, 5/1986 or U.S. Pat. # 4,531,519; U.S. Cl. 128-327, 7/1985) applied in surgery. They provide a more accurate control of the vein compression rate.

However, they cannot be secured directly on the venous junction. Besides, they are complex in design (with a remote pressure source) and relatively large-sized, so they cannot constantly and independantly operate inside the human body.

3. The Prior Art

Most similar to the present invention is the device disclosed in U.S. Pat. # 5,120,300; U.S. Cl. 602-61, 6/1992 and in the book "Plastic and reconstructive operations on great veins", by A.N. Vedensky, "Medizina", Leningrad, 1979, p. 186-194.

Said devices comprise bands (U.S. Pat. # 5,120,300) or spiral springs formed of plastic, metal, alloy or plastic reinforced with metal (lavsans, fluorineplastic etc.).

They can apply the given compression force to the vein around the insufficient valve.

The common drawbacks of said devices as well as of those described above are as follows:

1) they cannot be applied for correction of vein valves, disposed in the venous junctions;

2) they have only a compressing portion whereas no fixing means is provided to prevent axial displacement of the compressing member along the vein.

Besides, in some cases not only the valve correction in the venous junction is required but an additional correction of the insufficient vein area adjoining said junction.

An object of the present invention is to provide a device and method for a controlled correction of insufficient valve immediately in the venous junction, and, if necessary, of the insufficient valve in the area adjoining said junction.

Summary of the Invention

An object of the present invention is a device and method for external correction of insufficient valves in venous junctions.

The device is formed substantially from a single length of material as a band with a variable rigidity and vein compression rate, said band comprising at least one main compressing portion, and an intermediate and fastening portion, said main compression portion being disposable on the vein surface around the insufficient valve. Said band is shaped as a Mobius band. It may be formed of metal or alloy, such as one having a shape memory or spring effect.

The band can be also formed of plastic, metal coated plastic or plastic reinforced with metal or alloy. The band can be formed from two layers of flexible fluid-impermeable plastic welded together at their edges to form a cavity for a fluid or gas, at least one of said layers being reinforced with metal or alloy.

Said cavity can be divided into two or more hermetically isolated chamber.

There is an additional compressing portion adjoining the main compressing portion near the free end thereof,

said additional portion being disposable on the insufficient vein near said insufficient valve but on the side opposite to the venous junction.

5 The main and additional compressing portion can be formed as a bifurcated or branched end of said band.

Said additional compressing portion can be also formed as semirigid or resilient ekzovascular framework supporting and compressing the vein. This framework comprises a support member disposed substantially along the vein longitudinal axis and compressing ribs extending therefrom.

10 The additional compressing portion can be made of metal or alloy, of plastic, such as a metal coated plastic or one reinforced with metal or alloy. The device can be formed of a "Gore-tex" type plastic.

15 The compressing ribs of said additional compressing portion can be provided with means for fastening them together, such as male and female connectors.

Said hermetically isolated chambers can be disposed both within the whole device and within some of its portions only, such as the main and additional compressing portion or additionally within the intermediate and fastening portions. When said chambers are provided only within a part of said band, the rest of it is integral.

20 The method for external correction of insufficient valves in venous junctions according to the present invention comprises exposing, by routine technique, the venous junction, placing on the outside thereof the correction device, the main compressing portion being disposed close to the junction to fully encompass the vein on the outside around the insufficient valve, and the fastening portion disposed substantially on the adjacent vein.

Thereafter the blood flow in the vein is tested, and from the reflux value the necessary compression rate of the vein is determined.

35 To increase the compression rate, a biologically inert gas or a quickly solidifying, biologically inert fluid is injected into said chambers of said band cavity, adjusting

the size of the valve central opening, said size being checked by reflux in the vein.

If necessary, the manipulations with the injector are repeated, to increase or reduce pressure in said band chambers or in its entire cavity.

The need in applying the additional compressing portion and the required compression force are determined. If necessary, said portion is disposing on the vein, said portion length being adjusted by cutting off the redundant part. The available rib connectors of the additional compressing portion remaining part are fastening together in a certain manner, and said additional compressing portion is secured on the insufficient vein.

When application of said additional portion is not necessary, it is completely cut off. And, at last the final effect of correction is checked and the wound is closed by routine technique.

Brief Description of the Drawings

The above and other objects, features and advantages of the present invention will become more readily apparent from the following description, reference being made to the accompanying drawings in which:

Fig. 1 - is a general view of the device disposed on a venous junction;

Fig. 2 - is a general view of the device formed from plastic reinforced with metal;

Fig. 3 - is a fragmentary view of the plastic band reinforced with metal;

Fig. 4 - is a view of a pair of ribs on the additional compressing portion;

Fig. 5 - is the device embodiment formed as a Mobius band.

Specific Description

According to the present invention, the device (1) for correction of insufficient valves in venous junctions (2) comprises a band (3) with variable rigidity and vein (4)

compression rate. The band (3) includes a main compressing portion (5), an intermediate portion (6), a fastening portion (7) and an additional compressing portion (8) [Fig. 1].

5 The device formed of reinforced plastic is shown in Fig. 2.

 The band (3) of this device consist of two layers (9, 10) of fluid-impermeable plastic, one of said layers (9) being reinforced with metal or alloy wire (11). The layers
10 (9, 10) of the band (3) are welded at their edges forming an inner cavity (12). The latter is divided into two or more hermetically isolated chambers (13) [Fig. 2, 3].

 Near the free end (14) of the band (3) there is an additional compressing portion (8), comprising a support
15 member (15) and twin compressing ribs (16, 17) extending therefrom.

 The additional compressing portion (8) and the band (3) form a single piece made of reinforced plastic. On the support member (15) surface incisions (18) are made to mark
20 the spots of cutting off redundant pairs of compressing ribs (16, 17).

 The compressing ribs (16, 17), [Fig.4] are provided at their ends with male (19) and female (20) connectors for mutual securing.

25 The additional compressing portion (8) can be shaped as a spiral band integral with the band (3), [Fig. 5]. The band (3) can be shaped as a Mobius band, the bend (21) thereof being disposed substantially in the intermediate portion (6) area. In this case the additional compressing
30 portion (8) is shapes as a spiral (22) of reinforced plastic and adjoins the band (3) near the free end (14) thereof.

 The method for correction of insufficient valves in venous junction, based on the application of the above
35 device, comprises the steps of:-

 Exposing by routine surgical technique a venous junction with the insufficient valve, such as the Saphene-

Femoral Junction which unites the Common Femoral Vein, Superficial Femoral Vein and Great Saphene Vein;

Positioning the correction device outside the junction in such a way that the fastening portion (7) is disposed on the Common Femoral Vein, the main compressing portion (5) is close to the junction and encompasses valve of the Great Saphene Vein, said valve adjoining the Common Femoral Vein, and the intermediate portion (6) is disposed in the area where the Common Femoral Vein and Superficial Femoral Vein join.

Thereafter the reflux is determined and from its value the required correction value for the Great Saphene Vein value.

Subsequently, by means of an injector, portions of quickly solidifying, biologically inert fluid are introduced into the chambers (13) of the band (3), increasing the rigidity of the main compressing portion (5) and the compression force applied to the Great Saphene Vein around the valve thereof.

However, the solidified fluid has some resilience which prevents vein walls injuries.

The effect is checked, and if necessary the manipulation with the injector is repeated to increase or reduce fluid pressure in the chambers (13) or in the entire cavity (12).

If necessary, an additional compressing portion (8) is positioned on the Great Saphene Vein. Prior to positioning the device on said vein, its length and compression force are adjusted by cutting off the redundant part (or redundant end or intermediate ribs 16, 17 in the first embodiment of device 1). Portion (8) is secured on the Great Femoral Vein (in the first embodiment of device 1 by engaging the connectors 19, 20 in pairs). Unless the additional compressing portion (8) is not necessary, it is completely cut off.

After the fluid solidification in chambers (13) or cavity (12) of band (3) the final effect of the valve

correction is checked and the Saphene-Femoral Junction is closed by routine surgical technique.

Valves in other venous junctions are corrected likewise.

5 The above device and method allow to correct valves in venous junctions where it could not be done before due to the absence of special techniques.

The disclosed engineering solution is simple and reliable.

10 The correction device can be put to a mass industrial production applying the existing technology and materials, such as "Gore-tex" type plastic.

In the description of the specific embodiments of the invention shown in the drawings specific terms are used.
15 However every term specifies all equivalent members operating likewise and used to solve the same problems as the present invention.

Above we gave a description of preferred variants of the device. However, it should be clear that many improvements, changes and additions of equivalent members may be
20 introduced without depriving the present invention of its advantages cited in the claims.

Claims

1. A device for external correction of insufficient valves in venous junctions, comprising substantially a length of material shaped as a band with a variable rigidity and vein compression rate, said band having at least one main compressing portion, said main compressing portion being disposable onto the vein surface around the insufficient valve.
2. A device according to claim 1, wherein said band is shaped as a Mobius band.
3. A device according to claim 1, wherein said band is formed of metal or alloy.
4. A device according to claim 3, wherein said band is formed of metal or alloy with a spring effect.
5. A device according to claim 3, wherein said band is formed of a shape memory alloy.
6. A device according to claim 1, wherein said band is formed of plastic.
7. A device according to claim 6, wherein said band is formed of metal coated plastic.
8. A device according to claim 6, wherein said band is formed of plastic reinforced with metal or alloy.
9. A device according to claim 6, wherein said band is formed from two layers of flexible fluid-impermeable plastic welded together at their edges to form a cavity for a fluid or gas.
10. A device according to claim 9, wherein said band is formed from two layers of flexible fluid-impermeable

plastic welded together, at least one of said layers being reinforced with metal or alloy.

- 5 11. A device according to claim 9, wherein said band is formed from two layers of flexible fluid-impermeable plastic welded together, the cavity formed between said layers being divided into two or more hermetically isolated chambers.
- 10 12. A device according to claim 1, wherein said band has at least one additional compressing portion adjoining said main compressing portion near its free end, said additional compressing portion being disposable on an insufficient vein near the insufficient valve and on
15 the side opposite to the venous junction.
13. A device according to claim 12, wherein said main and additional compressing portions are formed each as a bifurcated or branched end of said band.
20
14. A device according to claim 12, wherein said additional compressing portion is formed as semirigid or resilient ekzovascular framework supporting and compressing the vein, said framework compressing a support member disposed substantially along the vein
25 longitudinal axis and compressing ribs extending therefrom.
15. A device according to claim 12, wherein said additional compressing portion is formed of metal or alloy
30 with spring effect or shape memory.
16. A device according to claim 12, wherein said additional compressing portion is formed of plastic.
35

17. A device according to claim 12, wherein said additional compressing portion is formed of plastic reinforced with metal or alloy.
- 5 18. A device according to claim 14, wherein said compressing ribs are provided with means for fastening them together, such as male and female connectors.
- 10 19. A device according to claim 6, wherein said band, comprising a main compressing portion, an intermediate and fastening portion, is formed of a "Gore-tex" type plastic.
- 15 20. A device according to claims 16 or 17, wherein said additional compressing portion is formed of a "Gore-tex" type plastic.
- 20 21. A device according to claim 11, wherein said isolated chambers are disposed only within the main compressing portion, and the rest of said band is integral.
- 25 22. A device according to claim 11, wherein said isolated chambers are disposed both within the main compressing portion and within the fastening and/or intermediate portion.
- 30 23. A device according to claims 11 and 16 or 17, wherein said isolated chambers are disposed within said additional compressing portion.
- 35 24. A method for external correction of insufficient valves in venous junctions, comprising the steps of:
(a) exposing, by routine technique, the venous junction and placing the correction device on the venous junction outside, so that the main compressing portion may be closed to the junction and fully encompass the vein on the outside

- around the insufficient valve, and the fastening portion be disposed substantially on the adjacent vein;
- 5 (b) determining the blood reflux in the vein with insufficient valves;
- (c) performing a gradual compression of the vein until the reflux disappears, such as by injecting portions of a biologically inert gas or quickly solidifying biologically inert fluid into the inner cavity or isolated chambers of said band inner cavity;
- 10 (d) checking the effect and, if necessary, repeating the manipulation, increasing or reducing compression in certain cambers of said band or compression of the whole band;
- 15 (e) determining the need in applying the additional compressing portion of said band and the required compression rate;
- (f) when application of the additional compressing portion is necessary, disposing and fastening the latter on the vein in a known manner, adjusting the compression rate and said portion length, cutting off its redundant piece and fastening together in a certain manner the available connectors of the remaining piece ribs;
- 20 (g) when the application of said band additional portion is not necessary, cutting off the whole portion;
- 25 (h) checking the final affect of correction and closing the wound by routine technique.
- 30

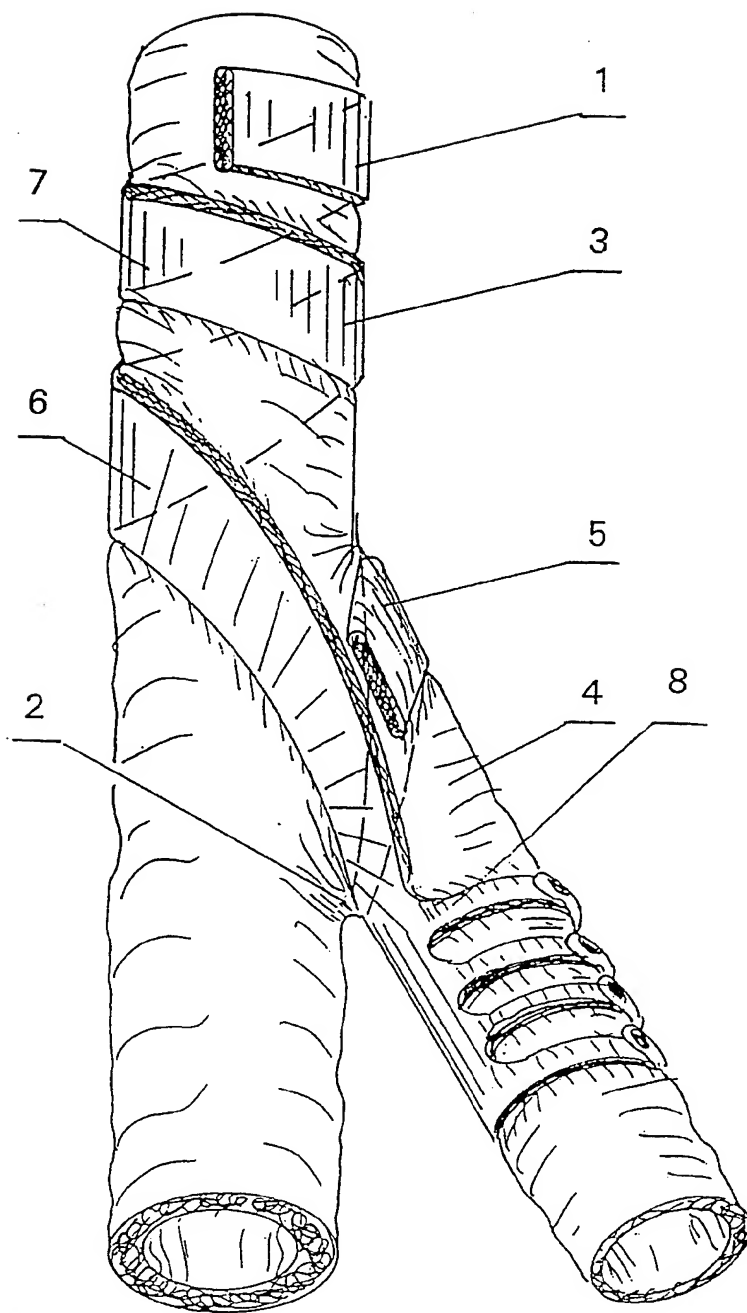


FIGURE 1

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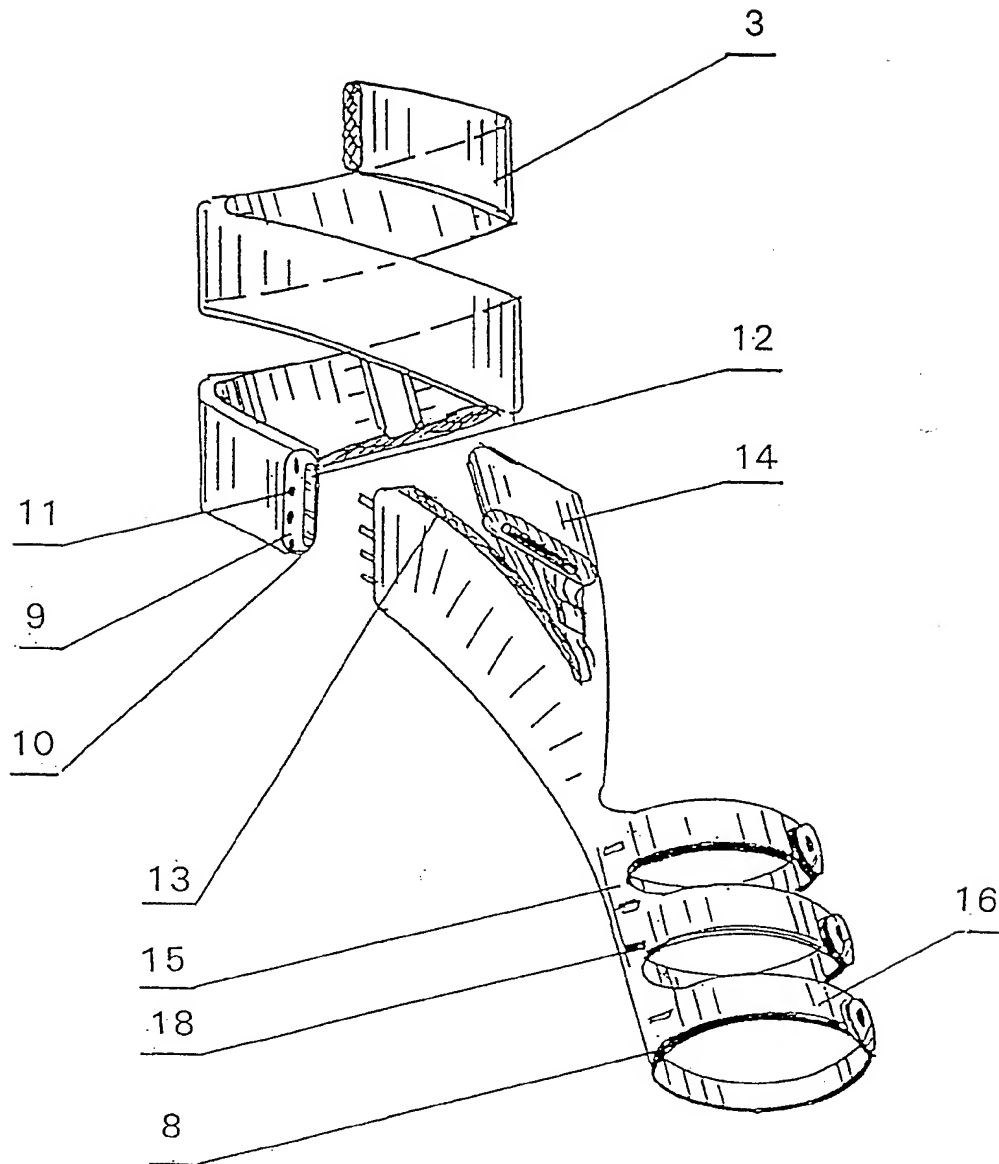


FIGURE 2

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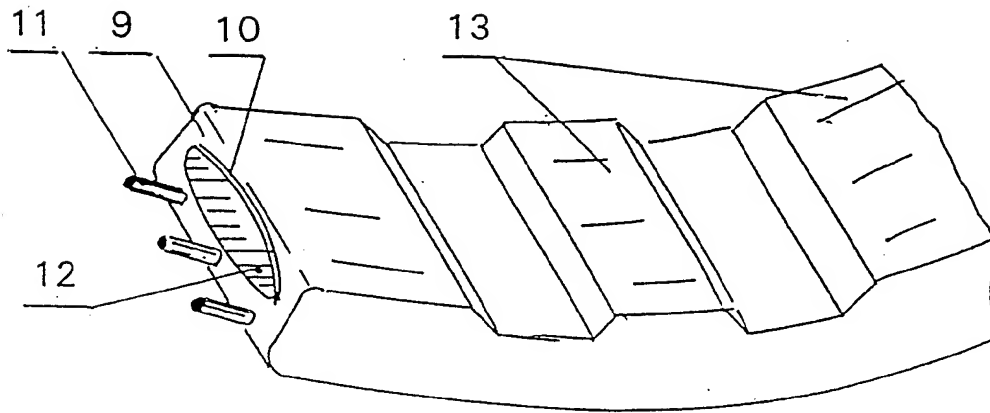


FIGURE 3

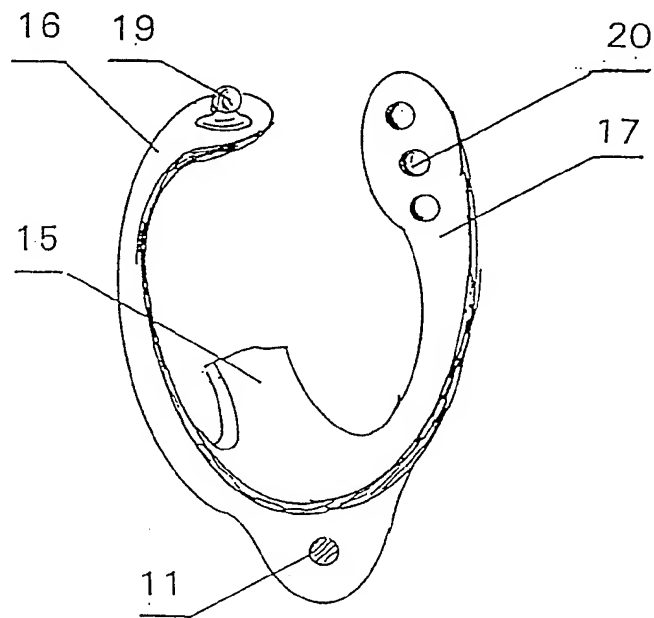


FIGURE 4

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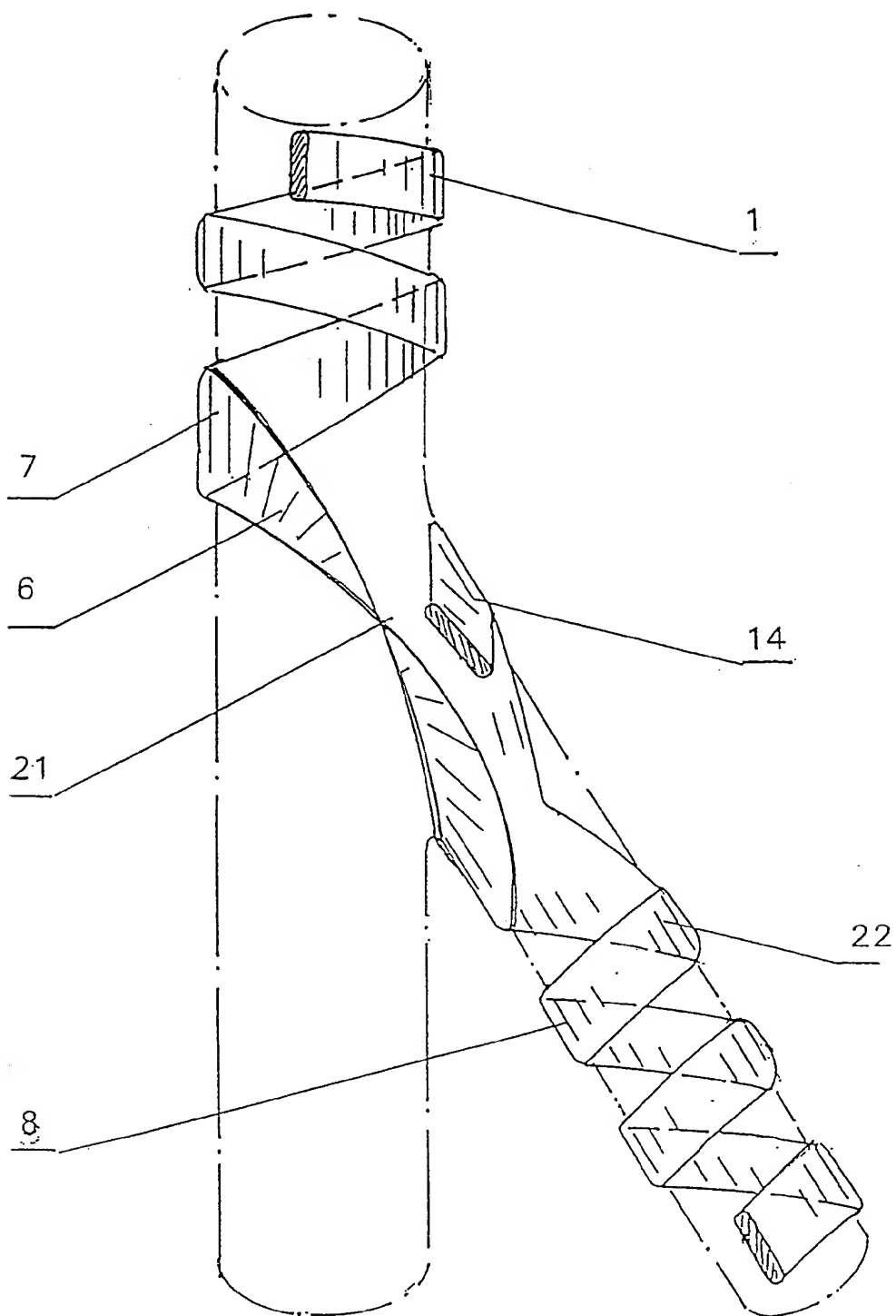


FIGURE 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP94/02750

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B 17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,3 726 279 (BAREFOOT ET AL.) 10 April 1973 see claim 1; figures 6,10 ---	1
A	US,A,4 881 939 (NEWMAN) 21 November 1989 see claim 1 ---	1
A	FR,A,2 211 208 (DOW CORNING CORP.) 19 July 1974 see claim 1 ---	1
A	WO,A,88 06026 (ARPESANI) 25 August 1988 -----	

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

13 December 1994

Date of mailing of the international search report

23.12.94

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP 94/02750

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 24
because they relate to subject matter not required to be searched by this Authority, namely:
see Rule 39.1 (iv) PCT
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

I. International Application No

PCT/EP 94/02750

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-3726279	10-04-73	NONE	
US-A-4881939	21-11-89	NONE	
FR-A-2211208	19-07-74	US-A- 3823705	16-07-74
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